

REMARKS

The claims are 1, 2, 7-18, 20-25, 28-30 and 34. Claims 1, 11 and 34 have been amended to more clearly define what is regarded as the invention with support located throughout the specification including, for example, at page 7, lines 18-27 and 33-35, page 8, lines 8-10 and page 10, lines 26-32. Favorable reconsideration is respectfully requested.

Applicants again thank the Examiner for the indication that Claims 20 and 21 include allowable subject matter and would be allowable if rewritten in proper independent form. However, these claims have not been rewritten for the reasons that follow.

In the Office Action, all of the prior rejections under 35 U.S.C. § 103(a) are maintained, with Claims 1, 2, 7-18, 22, 23, 28-30 and 34 alleged to be unpatentable over *Winskill et al.*, Animal Behavior Science 48:25-35 (1996) in view of *Johnson et al.*, Equine Veterinary Journal 30(2): 139-143 (1998), further in view of *Pagan*, Australian Equine Veterinarian 16(4): 159-161 (1998). Claims 24 and 25 likewise remain rejected under § 103(a) as allegedly unpatentable over *Johnson et al.*, and *Winskill et al.*, in view of *Pagan*. Applicants respectfully traverse these rejections.

The Office Action indicates that “Winskill teaches the composition of the instant claims except that [it] does not teach a feed composition that contains an antacid”, but suggests a combination with *Johnson* would be obvious since the latter “discloses that sodium carbonate, an antacid, can be administered to stabled horses”. Office Action, page 3.

As understood by Applicants, *Winskill* teaches that stereotypies may result from an inability to express foraging behavior, and that a feed of fiber and oil, together with a behavior enrichment device (*i.e.*, foodball), lower the incidence of such behavior.

The reference, however, is silent as to any link between pH generally and stereotypies. *Johnson*, meanwhile, discusses only a correlation between hindgut pH and abnormal behavior. To reduce the incidence of such behavior, the reference teaches “neutralising the acidity of the hind-gut of such animals by administering sodium carbonate to the caecum”. *Johnson*, page 139. Plainly, therefore, this combined teaching is limited to correlating only hindgut acidity with abnormal behavior. Yet, in contrast to the present claims, this combination of references does not suggest, much less teach, a possible link between stomach pH and stereotypy.

If the Examiner is referring to sodium carbonate as the antacid in *Johnson* to support the rejection of Claim 1, Applicants believe that one of ordinary skill would not have combined this compound with the feed of *Winskill* because sodium carbonate is conventionally administered to the caecum to neutralize hindgut acidity (*see Johnson*, page 139, right column, last sentence of second paragraph), and so would need to be administered separately from the feed. Indeed, at page 4, the Office Action acknowledges *Johnson* as teaching that “neutralizing acidity of the hindgut by administering sodium carbonate lowers the incidence of stereotypic behavior” (emphasis added). Thus, as amended, the limitation of an “oral feed composition” in Claim 1 would not be satisfied by a combination of the feed in *Winskill* with the sodium carbonate of *Johnson*.

In support of their argument, Applicants enclose a Declaration under 37 C.F.R. § 1.132, explaining that sodium carbonate merely reduces hindgut acidity, an altogether separate mechanism from that of the present invention. Any combination of sodium carbonate with the feed of *Winskill* would, therefore, result in the prior art being modified unsatisfactory for its intended purpose. As explained in the Declaration, the hindgut is a separate organ from the stomach, consisting of the colon and caecum. Oral

administration of sodium carbonate would therefore have a detrimental effect on the animal in the long term. Among the reasons against any such modification is (a) the likely increase in hindgut activity; (b) the expectation of the sodium carbonate being neutralized by the stomach acid; and (c) potential significant lactic acidosis. *See* Declaration, paras. 6 and 10-13. As such, Applicants believe there is no motivation to make the proposed modification, so as to render obvious the composition as claimed.

Claim 1 is amended to make clear that the composition is an oral feed composition, incompatible with caecal administration. Without any suggestion in either reference of a link between stomach pH and abnormal behavior, Applicants respectfully submit that the only possible teaching from the prior art would be oral administration of sodium carbonate for affecting hindgut pH (not stomach pH). Such action, however, would result in the sodium carbonate being neutralized by the acid in the stomach thereby rendering the resulting composition ineffective for its intended purpose. *See* Rowe et al., International Horse Industry Symposium, RIRDC, 2001, left page, point 4 (“Buffers such as sodium bicarbonate are unlikely to reach the hindgut as the acidic conditions in the stomach convert all bicarbonate to carbon dioxide and water.”). Accordingly, it is submitted that one of ordinary skill would not have administered sodium carbonate orally as part of a feed composition to neutralize hindgut acidity based on the teaching of the cited references. As a result, Claim 1 is believed patentable over the combination of *Winskill* and *Johnson*.

If, on the other hand, the Office Action refers to the Founderguard in *Johnson*, it is respectfully submitted that the virginiamycin contained in the Founderguard does not constitute a “stomach antacid.” *Johnson* does not disclose administration of feed/food containing stomach antacid, but only dietary supplementation with virginiamycin

to reduce fermentative acidosis in the hindgut. Virginiamycin, however, is a streptogramin antibiotic, specifically active against bacteria that ferment carbohydrates to produce lactic acid primarily in the hindgut. *See* Declaration, para. 14. Yet, the primary cause of acidity in the stomach is secretion of hydrochloric acid. Consequently, if administration of virginiamycin has any significant effect on gastrointestinal pH, it is expected that this would be against hindgut, rather than stomach, acidity.

Notably, nothing in *Johnson* would lead one of ordinary skill to replace virginiamycin with an orally-administered stomach antacid so as to make obvious Claim 1, because there is no disclosure in this document of a link between stomach acidity and abnormal behavior. As explained in the Declaration, the mere disclosure of a link between hindgut acidity and abnormal behavior does not mean that there is also necessarily a link between stomach acidity and stereotypy—a further consequence of the physiological differences between the hindgut and stomach.

The Office Action states that *Winskill's* feed composition, though containing no antacid, was effective in combination with the foodball to increase foraging time and thus lowered stereotypy. The Examiner then comments that a composition can be formulated from the combination of *Winskill* and *Johnson* as a feed for horses, and the motivation of including the antacid of *Johnson* is to produce a feed that would be expected to lower the incidence of stereotypy.

Respectfully, the combination of the feed of *Winskill* with the antacid of *Johnson* (*i.e.*, virginiamycin) does not produce a composition within the scope of present Claim 1 because virginiamycin is not believed to be a stomach antacid. Furthermore, the feed of *Winskill* with the antacid of *Johnson* would not be expected to control stomach pH (for the reasons given in the enclosed Declaration); only hindgut acidity. Accordingly, it is

respectfully submitted that Claim 1 is not obvious over the teaching of *Winskill* with *Johnson*.

The Office Action further alleges that “Johnson and Winskill clearly teach the method of the instant claims except that the [combination] . . . does not teach administering proton pump inhibitor or histamine type-2 antagonist . . . [b]ut, Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists . . . or proton pump inhibitors”. Office Action, page 4. Applicants respectfully submit that Claims 11 and 34 are patentable over the combination of *Winskill* and *Johnson*, together with *Pagan*.

As amended, the methods of Claims 11 and 34 are directed to lowering stereotypy by controlling stomach pH through oral administration of a “stomach antacid” and a “composition comprising fat, fibre, and optionally, a stomach antacid”, respectively. At pages 4-5, the Office Action alleges that “it would have been obvious . . . at the time the invention was made to use the composition of Winskill to treat stereotypic behavior and to incorporate antacid of Johnson or Pagan with the expectation of lowering or reducing the acidity of the hindgut” (emphasis added) and indicates that the motivation to combine the teachings with *Pagan* is to “lower the incidence of stereotypic behavior and with the expectation that the histamine type-2 antagonists and proton pump inhibitor will reduce or inhibit gastric secretion”. Applicants respectfully disagree.

Pagan likewise fails to recognize any link between stomach pH and stereotypy.¹ Absent such teaching, Applicants believe that one of ordinary skill would not combine this reference with *Winskill* and *Johnson* since all three classes of antacids recited

^{1/} In addition, *Pagan* altogether fails to recognize any correlation between pH generally and stereotypies.

in *Pagan* are administered orally. As a result, *Pagan* directly conflicts with the teaching in *Johnson* that hindgut pH affects behavior, thereby lacking the required expectation of success to support a rejection under § 103(a). “Where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another.” MPEP § 2143.01 at 2100–136 (citing *In re Young*, 927 F.2d 588 (Fed. Cir. 1991)). As well, “impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” *Id.* at 2100–134. Applicants respectfully believe that the absence from *Pagan* of any suggestion with regard to behavior and pH would lead a person of ordinary skill to dismiss this reference when working from *Winskill* and *Johnson* to reduce or ameliorate animal stereotypy.

In particular, Claims 11 and 34 require oral administration for practicing the respective methods. However, one of ordinary skill is not taught by *Winskill*, *Johnson*, or *Pagan*, to administer sodium carbonate or sodium bicarbonate orally to cause a reduction in hindgut acidity. The enclosed Declaration provides further evidence against oral administration of sodium carbonate or sodium bicarbonate to reduce hindgut acidity.

In maintaining the rejections under § 103(a), the Examiner refers to the histamine type-2 antagonists of *Pagan*. These compounds block histamine-stimulated gastric acid secretion and so are expected to act as stomach antacids, but not to have any significant effect in the hindgut as the cited references suggest. Similarly, as the Declaration makes clear, virginiamycin is expected to reduce fermentative acidosis in the hindgut, but not to have any significant effect on stomach acidity. Without any disclosure of a link between stomach acidity and animal stereotypy in the cited art, whether alone or

in combination, one of ordinary skill would not have administered antacids expected to affect stomach acidity alone in order to treat animal stereotypy with a reasonable expectation of success.

More precisely, a person of ordinary skill in the art would not have substituted oral administration of virginiamycin or caecal administration of sodium carbonate (intended to control hindgut acidity) for oral administration of sodium carbonate or sodium bicarbonate in view of the significant physiological differences between the hindgut and stomach, recognized by those of ordinary skill. Such differences, together with the absence of any suggestion in the cited art of a correlation between stomach pH and stereotypy are believed to preclude a finding of obviousness. Claims 11 and 34 are therefore believed patentable over the cited art.

Moreover, in responding to Applicants' previously-submitted arguments, the Examiner comments that the "claims do not state that stereotypy is lowered or minimized or ameliorated by administering fiber and oil composition", and states that the argument that *Winskill* does not recognize that fiber and oil composition is effective in treating stereotypy is not within the scope of the examined claims. Yet, Applicants kindly draw the Examiner's attention to the fact that both Claims 11 and 34 explicitly recite oral administration "to treat or ameliorate stereotypy in the animal, or to minimize the risk of the animal developing animal stereotypy." Accordingly, Applicants' argument that *Winskill* does not recognize that fiber and oil composition is effective in treating stereotypy is believed relevant to the examined claims.

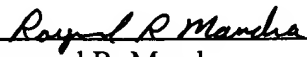
In sum, nothing in the cited art is believed to teach or suggest either a link between stomach acidity and stereotypy generally or providing a composition with a stomach antacid, fat and fiber as specifically recited in the present claims. Based on the

foregoing, Applicants therefore submit that Claims 1, 11 and 34, together with the claims dependent thereon, are patentable over *Winskill* and *Johnson*, further in view of *Pagan*. Independent Claims 2 and 24 are likewise believed patentable by virtue of at least the same reasons advanced above. Accordingly, withdrawal of the present rejections is kindly requested.

Wherefore, it is respectfully submitted that the presently claimed invention is not disclosed or suggested by the art of record whether taken alone or together. Accordingly, it is respectfully requested that the claims be allowed and the case passed to issue.

Applicants' undersigned attorney may be reached in our New York Office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address listed below.

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